



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,158	09/15/2003	Frederic DeSavage	11669.123USC1	4053
23552 7590 03/22/2007 MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER SKELDING, ZACHARY S	
			ART UNIT	PAPER NUMBER
			1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/22/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.



### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed September 27, 2006 has been entered.
2. Applicant's amendment to the claims, filed September 27, 2006, has been entered.

Claims 35 has been amended.

Claims 2-34 have been canceled.

Claims 36-68 have been added.

Claims 1 and 35-68 are pending.

Claims 35, 49, 50 and 57-59 are under examination as they read on a method for inhibiting the differentiation of Th0 cells into a Th2 subtype comprising administering an anti-TCCR antibody agonist.

Claims 1, 36-48, 51-56 and 60-68 are withdrawn as being drawn to a non-elected invention.

3. *Upon further consideration, the following supplemental species election is set forth as it reads on the elected invention.*

*The Examiner apologizes for any inconvenience to applicant in this matter.*

### *Species Election*

5. This application contains claims generic to patentably distinct species of the claimed invention. Applicant is **required to elect if the claimed method comprises administration of:**
  - A. an antibody that agonizes murine TCCR and variants thereof, such as SEQ ID NO: 1
  - OR
  - B. an antibody that agonizes human TCCR and variants thereof, such as SEQ ID NO: 2.

Art Unit: 1644

Related inventions are patentably distinct if the inventions *as claimed* are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER (though they may each be unpatentable over the prior art). See MPEP § 802.01.

In the instant case, the instantly claimed methods comprise administration of agonistic antibodies that bind patentably distinct antigens. The polypeptide antigens bound by the instantly claimed antibodies are structurally different in that they share just 62% identity across 618 amino acids with no appreciable identity at their N and C termini (see attached alignment).

Moreover, the physiochemical properties of these polypeptides are different, and/or they do not share a common structure that is disclosed to be essential for common utility, and in turn antibodies that recognize these polypeptides are patentably distinct. Indeed, one post-filing date anti-TCCR antibody generated using human TCCR polypeptide antigen, the 2686 antibody, recognizes, and appears to induce TCCR signaling in Ba/F3 cells; however the 2686 antibody does not bind/induce signaling of murine TCCR (see US20060177436, page 19, paragraph [0219], cited herewith).

Furthermore, examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

*If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.*

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

Art Unit: 1644

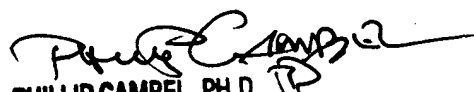
examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.  
Patent Examiner  
March 19, 2007

  
PHILLIP GAMBEL, PH.D.  
PRIMARY EXAMINER  
R-600

3/19/07

2 page alignment  
attached TS.  
3-19-07

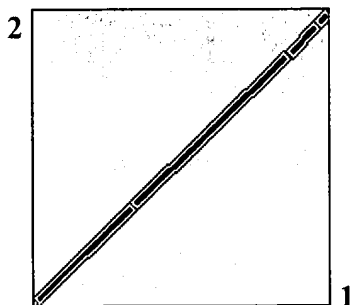
## BLAST 2 SEQUENCES RESULTS VERSION BLASTP 2.2.15 [Oct-15-2006]

Matrix:  gap open:  gap extension:   
 x\_dropoff:  expect:  wordsize:  Filter ☐ View option:   
 Masking character option:  Masking color option:   
☐ Show CDS translation

Sequence 1: lcl|1\_sin2  
 Length = 623 (1 .. 623)

Sequence 2: lcl|2\_sin1  
 Length = 636 (1 .. 636)

MOUSE VS. HUMAN TCCR



NOTE: Bitscore and expect value are calculated based on the size of the nr database.



Score = 789 bits (2037), Expect = 0.0  
 Identities = 388/618 (62%), Positives = 449/618 (72%), Gaps = 8/618 (1%)

Query	9	LTPLELLLSLMSLLLGTRPHGSPGPLQCYSVGPLGILNCSWEPLGDLETPPVLYHQSQKY	68
		L L LL L L TRP GS GPLQCY VGPLG LNCSWEPLGDL P L+ QSQKY	
Sbjct	14	LPKLALLPLLWVLFQRTRPQGSAGPLQCYGVGPLGDLNCSWEPLGDLGAPSELHLQSQKY	73
Query	69	HPNRVWEVKVPSKQSWVTIPREQFTMADKLLIWGTQKGRPLWSSVSVNLETQMKPDTPQI	128
		N+ V V + +SWV IPREQ TM+DKLL+WGT+ G+PLW V VNLETQMKP+ P++	
Sbjct	74	RSNKTQTVAVAAGRSWVAIPREQLTMSDKLLVWGTKAGQPLWPPVFNLETQMKPNAPRL	133
Query	129	FSQVDISEEATLEATVQWAPPVWPPQKALTCQFRYKECQAEAWTRLEPQLKTDGLTPVEM	188
		VD SE+ LEATV WAPP WP K L CQF Y+ CQ AWT LEP+LKT LTPVE+	
Sbjct	134	GPDVDFSEDDPLEATVHWAPPTWPSHKVLICQFHYRRCEAAWTLLEPELKTIPVET	193
Query	189	QNLEPGTCYQVSGRCQVENGYP-WGEWSSPLSFQTPFLDPEDVWVSGTVCETSGKRAALL	247
		Q+LE T Y+V GRC++E WGEWS LSFQTP P+DVWVSG +C T G LL	
Sbjct	194	QDLELATGYKVYGRCRMEKEEDLWGEWSPILSFQTPPSAPKDVWVSGNLCTPGGEEPLL	253
Query	248	VWKDPRPCVQVTYTVWFGAGDITTTQEEVPCKSPVPAWMEWAVVSPGNSTSWVPPTNLS	307
		+WK P PCVQV+Y VWF G + E + CC S +P+ EWA VS N+TSW P TNLS	
Sbjct	254	LWKAPGPCVQVSYKVVFWVGGRELSPEGITCCCSLIPSGAEWARVSAVNATSWEPLTNLS	313
Query	308	LVCLAPESAPCDVGVSADGSPGIKVTWKQGTTRKPLEYVVDWAQDGDSDLKLNWTRLPPG	367

		LVCL SAP V VSS GS + VTW+ G +PLE+VVDWA+DGD L+KLNW RLPPG	
Sbjct	314	LVCLDSASAPRSVAVSSIAGSTELLVTWQPGPGEPLEHVVDWARDGDPLEKLNWVRLPPG	373
Query	368	NLSTLLPGFEFKGGVPYRITVTAVYSGGLAAAPSVWGFREELVPLAGPAVWRLPDDPPGTP	427
		NLS LLPG F GVPYRITVTAV + GLA+A SVWGFREEL PL GP +WRL D PPGTP	
Sbjct	374	NLSALLPGNFTVGVYRITVTAVSASGLASASSVWGFREELAPLVGPTLWRLQDAPPGTP	433
Query	428	VVAWGEVPRHQLRGQATHYTFCIQSRGLSTVCRNVSSQTQTATLPNLHSGSFKLWVTVST	487
		+AWGEVPRHQLRG THYT C QS +VC NVS TQ+ TLP+L G +LWVT ST	
Sbjct	434	AIAWGEVPRHQLRGHLTHYTLCQSGTSPSVCNMVSGNTQSVTLPDLPWGPCELWVTAST	493
Query	488	VAGQGPPGPDLSLHLPDNRIRWKALPWFLSLWGLLLMGCGLSLASTRCLQARCLHWRHKL	547
		+AGQGPPGP L LHLPDN +RWK LP L LWGL L+GCGLSLA++ RC H RHK+	
Sbjct	494	IAGQGPPGPILRLHLPDNTLRWKVLPGILFLWGLFLLGCGLSLATS----GRCYHLRHKV	549
Query	548	LPQWIWERPDPANSNSGQPYIKEVSLPQPPKDGPILEVVEEVELQPVVES---PKASAPI	604
		LP+W+WE+VPDPANS+SGQP+++V QP D PILEVEE+E PV+ES +A+AP+	
Sbjct	550	LPRWVWEKVPDPANSSSGQPHMEQVPEAQPLGDLPILEVEEMEPPPMESSQPAQATAPL	609
Query	605	YSGYEKHFLPTPEELGLL	622
		SGYEKHFLPTPEELGLL	
Sbjct	610	DSGYEKHFLPTPEELGLL	627

CPU time: 0.04 user secs. 0.00 sys. secs 0.04 total secs.

Lambda	K	H
0.317	0.135	0.450

Gapped

Lambda	K	H
0.267	0.0410	0.140

Matrix: BLOSUM62  
Gap Penalties: Existence: 11, Extension: 1  
Number of Sequences: 1  
Number of Hits to DB: 4813  
Number of extensions: 2613  
Number of successful extensions: 4  
Number of sequences better than 10.0: 1  
Number of HSP's gapped: 1  
Number of HSP's successfully gapped: 1  
Length of query: 623  
Length of database: 1,634,373,987  
Length adjustment: 142  
Effective length of query: 481  
Effective length of database: 1,634,373,845  
Effective search space: 786133819445  
Effective search space used: 786133819445  
Neighboring words threshold: 9  
X1: 16 ( 7.3 bits)  
X2: 129 (49.7 bits)  
X3: 129 (49.7 bits)  
S1: 41 (21.6 bits)  
S2: 82 (36.2 bits)